 K110841

510(k) Summary

APR 15 2011

This summary of 510(k) safety and effectiveness information is provided in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

The assigned 510(k) number is: _____

1. 510(k) Owner:

Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI)
77 Jinsha Road, Shantou, Guangdong 515041, China
Tel: 86-754-88250150 Fax: 86-754-88251499

Contact Person:

Flower Cai
Shantou Institute of Ultrasonic Instruments Co., Ltd.
77 Jinsha Road, Shantou, Guangdong 515041, China

Date Prepared: March 22, 2011

2. Device/Trade Name:

Apogee 3800 Digital Color Doppler Ultrasound Imaging System

Classification Name:

Regulatory Class: II

Ultrasonic Pulsed Doppler Imaging System	IYN	(per 21 CFR 892.1550)
Ultrasonic Pulsed Echo Imaging System	IYO	(per 21 CFR 892.1560)
Diagnostic Ultrasound Transducer	ITX	(per 21 CFR 892.1570)

3. Legally Marketed (Unmodified) Device Predicate Device:

The subject device is modified based on and substantially equivalent to the device currently having FDA 510(k)' clearance SIUI Apogee 3500 Digital Color Doppler Ultrasound Imaging System, K102023 with respect to intended use, principles of operation and technological characteristics.

4. Device Description:

The SIUI Apogee 3800 is a Digital Ultrasound Imaging System capable of the following operating modes: 2D (B mode), M, Doppler (PWD mode), Color (CFM mode) and 3D. The system is designed for use in linear, convex, phased array and 3D scanning modes and supports linear, convex, phased array and 3D transducers. The system has cine review, image zoom, measurements and calculations, image storage and review, printing and recording capabilities.

5. Intended Use:

The device is intended for ultrasonic pulsed echo imaging and measurement for abdominal, pediatric, small organs, musculo-skeletal, cardiac and peripheral vascular applications.

6. Safety Considerations:

The Apogee 3800 Digital Color Doppler Ultrasound Imaging System has been tested per the FDA Guidance document *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* issued in September 2008.

The device conforms to applicable medical device safety standards. It has been designed to meet the following standards: NEMA UD 2, UD 3, IEC 60601-1, ISO10993-5 and ISO 10993-10.

7. Conclusion:

The conclusions drawn from testing of the Apogee 3800 Digital Color Doppler Ultrasound Imaging System demonstrates that the device is as safe and effective as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ms. Flower Cai
Assistant to Director
Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI)
77 Jinsha Road
Shantou, Guangdong, 515041
CHINA

APR 15 2011

Re: K110841
Trade/Device Name: Apogee 3800 Digital Color Doppler Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: March 23, 2011
Received: March 25, 2011

Dear Ms. Cai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Apogee 3800 Digital Color Doppler Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

Convex Array C3L60C
Linear Array L8L38C
Convex Array C5L40C
Phased Array P3F14C

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K110841

Device Name:

Apogee 3800 Digital Color Doppler Ultrasound Imaging System with

Convex Array Transducer C3L60C

Linear Array Transducer L8L38C

Convex Array Transducer C5L40C

Phased Array Transducer P3F14C

Indications for Use:

Diagnostic ultrasonic imaging for abdominal, pediatric, small organ, musculo-skeletal, cardiac, peripheral vascular applications in B, M, PWD, Color Doppler and 3D imaging modes.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110841

Diagnostic Ultrasound Indications for Use Form

5.1 System Indications for Use Form

System: Apogee 3800

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N		N
	Abdominal	N	N	N		N		N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N		
	Small Organ (Specify)	N	N	N		N		
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N		
	Musculo-skeletal (Superficial)	N	N	N		N		
	Intravascular							
	Other (Specify)	N	N	N		N		N
Cardiac	Cardiac Adult	N	N	N		N		
	Cardiac Pediatric	N	N	N		N		
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N		
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Other modes of operation include: 3-D Imaging;

Additional Comments: Other uses include: Prostate, Kidney, Uterus, Ovary
Small organs include: Thyroid, Testes, Breast

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110841

Diagnostic Ultrasound Indications for Use Form

5.2 Transducer Indications for Use Form

Transducer: Convex Array C3L60C

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N		
	Abdominal	N	N	N		N		
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)	N	N	N		N		
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
Additional Comments: Other uses include: Prostate, Kidney, Uterus, Ovary

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110841

Diagnostic Ultrasound Indications for Use Form

5.3 Transducer Indications for Use Form

Transducer: Linear Array L8L38C

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N		
	Small Organ (Specify)	N	N	N		N		
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**	N	N	N		N		
	Musculo-skeletal **(Superficial)**	N	N	N		N		
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N		
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
Additional Comments: Small organs include: Thyroid, Testes, Breast

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110841

Diagnostic Ultrasound Indications for Use Form

5.4 Transducer Indications for Use Form

Transducer: Convex Array C5L40C

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal		N					N
	Abdominal		N					N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)		N					N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes include: 3-D Imaging;
Additional Comments: Other uses include: Prostate, Kidney, Uterus, Ovary

Prescription Use (Per 21 CFR 801.109)

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510K K110841

Diagnostic Ultrasound Indications for Use Form

5.5 Transducer Indications for Use Form

Transducer: Phased Array P3F14C

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N		
	Cardiac Pediatric	N	N	N		N		
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Prescription Use (Per 21 CFR 801.109)

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